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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

TOM HILAMAN and LUCRETIA SHIVERS,
Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.),
and MONSANTO COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-04383-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"¹)
3 ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file their
4 Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as
5 follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used
9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the
11 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of
20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,
21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used

24 _____
25 ¹ Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity
26 known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31,
27 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company,
28 Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag
Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed
Celebrex®. Given that Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing
Celebrex®, see PLAINTIFFS' COMPLAINT at ¶ 6, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As
a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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1 in accordance with its FDA-approved prescribing information. Defendants state that the
2 potential effects of Celebrex® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
5 Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the
6 Complaint.

7 2. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
11 and deny the remaining allegations in this paragraph of the Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
14 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
16 and deny the remaining allegations in this paragraph of the Complaint.

17 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of
18 business in New York. Defendants admit that, as the result of a merger in April 2003,
19 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph
20 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants
21 are without knowledge or information sufficient to form a belief as to the truth of such
22 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of
23 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to
24 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
25 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 5. Defendants admit that Searle is a Delaware limited liability company with its principal
28 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,

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1 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
2 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
3 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
6 the remaining allegations in this paragraph of the Complaint.

7 6. Defendants admit that in 1933 an entity known as Monsanto Company (“1933
8 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
9 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name
10 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,
11 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company
12 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged
13 in the agricultural business and does not and has not ever manufactured, marketed, sold, or
14 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either
15 Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed,
16 sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a
17 proper party in this matter. Defendants deny the remaining allegations in this paragraph of the
18 Complaint. Defendants state that the response to this paragraph of the Complaint regarding
19 Monsanto is incorporated by reference into Defendants’ responses to each and every paragraph
20 of the Complaint referring to Monsanto and/or Defendants.

21 7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
22 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
23 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
24 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
25 Celebrex® in the United States, including California, to be prescribed by healthcare providers
26 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28

Response to Allegations Regarding Jurisdiction and Venue

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

10. Defendants are without knowledge or information to form a belief as to the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the States of California, Florida, and North Carolina, and deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the State of and California. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny

1 the same. Defendants deny committing a tort in the States of California, Florida, and North
2 Carolina, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Allegations Regarding Interdistrict Assignment**

4 12. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendants
6 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
7 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
8 Panel on Multidistrict Litigation on September 6, 2005.

9 **Response to Factual Allegations**

10 13. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 14. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
22 Celebrex® was expected to reach users and consumers without substantial change from the
23 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 15. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
3 remaining allegations in this paragraph of the Complaint.

4 16. Defendants state that the allegations in this paragraph of the Complaint regarding
5 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no
6 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,
7 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the
8 remaining allegations in this paragraph of the Complaint.

9 17. Defendants state that the allegations in this paragraph of the Complaint are not directed
10 towards Defendants and, therefore, no response is required. To the extent that a response is
11 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
15 towards Defendants and, therefore, no response is required. To the extent that a response is
16 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
18 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19 19. Defendants state that the allegations in this paragraph of the Complaint are not directed
20 towards Defendants and, therefore, no response is required. To the extent that a response is
21 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
22 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
23 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

24 20. Defendants state that the allegations in this paragraph of the Complaint are not directed
25 towards Defendants and, therefore, no response is required. To the extent that a response is
26 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
27 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
28 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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21. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

22. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis

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1 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
2 the remaining allegations in this paragraph of the Complaint.

3 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
4 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
5 Celebrex® in the United States to be prescribed by healthcare providers who are by law
6 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
7 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
8 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
9 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
10 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
11 and effective when used in accordance with its FDA-approved prescribing information.
12 Defendants state that the potential effects of Celebrex® were and are adequately described in its
13 FDA-approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations in this paragraph of the Complaint.

16 25. Defendants state that the referenced article speaks for itself and respectfully refer the
17 Court to the article for its actual language and text. Any attempt to characterize the article is
18 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
20 this paragraph of the Complaint.

21 26. Defendants state that the referenced article speaks for itself and respectfully refer the
22 Court to the article for its actual language and text. Any attempt to characterize the article is
23 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
25 this paragraph of the Complaint.

26 27. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny the allegations in this paragraph of the Complaint.

3 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 29. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
10 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
11 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
12 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
13 and respectfully refer the Court to the study for its actual language and text. Any attempt to
14 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
15 the Complaint.

16 30. Defendants state that the referenced Medical Officer Review speaks for itself and
17 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
18 attempt to characterize the Medical Officer Review is denied. Defendants state that the
19 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court
20 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to
21 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 31. Defendants state that the referenced study speaks for itself and respectfully refer the
24 Court to the study for its actual language and text. Any attempt to characterize the study is
25 denied. Defendants state that the referenced article speaks for itself and respectfully refer the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

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32. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Plaintiffs fail to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 38. Defendants admit that there was a clinical trial called APC. Defendants state that the
3 referenced article speaks for itself and respectfully refer the Court to the article for its actual
4 language and text. Any attempt to characterize the article is denied. Defendants deny the
5 remaining allegations in this paragraph of the Complaint.

6 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
7 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
8 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 40. Defendants state that the referenced Medical Officer Review speaks for itself and
11 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
12 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
13 allegations in this paragraph of the Complaint.

14 41. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide
15 the proper context for the allegations concerning “other Celebrex trials” contained in this
16 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
17 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
18 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
19 that the referenced study speaks for itself and respectfully refer the Court to the study for its
20 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
21 remaining allegations in this paragraph of the Complaint.

22 42. Defendants state that the referenced article speaks for itself and respectfully refer the
23 Court to the article for its actual language and text. Any attempt to characterize the article is
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 43. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
26 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
27 therefore lack sufficient information or knowledge to form a belief as to the truth of such
28 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for

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1 themselves and respectfully refer the Court to the studies for their actual language and text.
2 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
3 this paragraph of the Complaint.

4 44. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 45. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®
9 in this paragraph of the Complaint are not directed toward Defendants, and therefore no
10 response is required. To the extent that a response is deemed required, Plaintiffs fail to provide
11 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in
12 this paragraph of the Complaint. Defendants therefore lack sufficient information or
13 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
14 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
15 the study for its actual language and text. Any attempt to characterize the study is denied.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 46. Defendants state that allegations in this paragraph of the Complaint regarding Merck
18 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and
19 therefore no response is required. To the extent that a response is deemed required, Plaintiffs
20 fail to provide the proper context for the allegations in this paragraph of the Complaint
21 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
22 sufficient information or knowledge to form a belief as to the truth of such allegations and,
23 therefore, deny the same. Defendants state that the referenced study speaks for itself and
24 respectfully refer the Court to the study for its actual language and text. Any attempt to
25 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
26 the Complaint.

27 47. Defendants state that allegations in this paragraph of the Complaint regarding Merck
28 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and

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1 therefore no response is required. To the extent that a response is deemed required, Plaintiffs
2 fail to provide the proper context for the allegations in this paragraph of the Complaint
3 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
4 sufficient information or knowledge to form a belief as to the truth of such allegations and,
5 therefore, deny the same. Defendants state that the referenced study speaks for itself and
6 respectfully refer the Court to the study for its actual language and text. Any attempt to
7 characterize the study is denied. Defendants state that the referenced article speaks for itself
8 and respectfully refer the Court to the article for its actual language and text. Any attempt to
9 characterize the article is denied. Defendants deny the remaining allegations in this paragraph
10 of the Complaint.

11 48. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants deny the allegations in this
13 paragraph of the Complaint.

14 49. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 50. Defendants state that allegations in this paragraph of the Complaint are not directed
18 toward Defendants, and therefore no response is required. To the extent that a response is
19 deemed required, Defendants state that the referenced article speaks for itself and respectfully
20 refer the Court to the article for its actual language and text. Any attempt to characterize the
21 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 51. Defendants deny the allegations in this paragraph of the Complaint.

23 52. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
28 remaining allegations contained in this paragraph of the Complaint.

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53. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

54. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

55. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

56. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

57. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants admit that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to

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1 characterize the transcripts is denied. Defendants state that the referenced study speaks for
2 itself and respectfully refer the Court to the article for its actual language and text. Any attempt
3 to characterize the article is denied. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 58. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
10 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
11 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
12 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
13 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
14 United States to be prescribed by healthcare providers who are by law authorized to prescribe
15 drugs in accordance with their approval by the FDA. Defendants deny the remaining
16 allegations in this paragraph of the Complaint.

17 59. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe
27 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
28 prescription medication which is approved by the FDA for the following indications: (1) for

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1 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
2 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
3 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
4 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
5 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
6 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
7 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint.

9 60. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which at all times was adequate and comported with applicable standards of care and law.
13 Defendants state that Plaintiffs' allegations in this paragraph of the Complaint regarding
14 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
15 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
17 allegations in this paragraph of the Complaint.

18 61. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe
28

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1 drugs in accordance with their approval by the FDA. Defendants deny the remaining
2 allegations in this paragraph of the Complaint.

3 62. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which at all times was adequate and comported with applicable standards of care and law.
7 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
8 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
11 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
12 United States to be prescribed by healthcare providers who are by law authorized to prescribe
13 drugs in accordance with their approval by the FDA. Defendants deny the remaining
14 allegations in this paragraph of the Complaint.

15 63. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 64. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 65. Defendants deny the allegations in this paragraph of the Complaint.
28

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66. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
8 the study for its actual language and text. Any attempt to characterize the study is denied.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 72. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® are and were adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 **Response to First Cause of Action: Negligence**

20 73. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
21 Complaint as if fully set forth herein.

22 74. Defendants state that this paragraph of the Complaint contains legal contentions to
23 which no response is required. To the extent that a response is deemed required, Defendants
24 admit that they had duties as are imposed by law but deny having breached such duties.
25 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
26 FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 75. Defendants state that this paragraph of the Complaint contains legal contentions to
4 which no response is required. To the extent that a response is deemed required, Defendants
5 admit that they had duties as are imposed by law but deny having breached such duties.
6 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
7 FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 76. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint, including all subparts.

18 77. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 78. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 79. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 80. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
15 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
16 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
17 paragraph of the Complaint.

18 81. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 82. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Second Cause of Action: Strict Liability**

23 83. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
24 Complaint as if fully set forth herein.

25 84. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
27 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
28 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be

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1 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
2 with their approval by the FDA. Defendants admit that, during certain periods of time,
3 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
4 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
5 providers who are by law authorized to prescribe drugs in accordance with their approval by the
6 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
7 consumers without substantial change from the time of sale. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 85. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 86. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
19 remaining allegations in this paragraph of the Complaint.

20 87. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
25 remaining allegations in this paragraph of the Complaint, including all subparts.

26 88. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny that Celebrex® is unreasonably dangerous and deny the remaining allegations
3 in this paragraph of the Complaint.

4 89. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
12 remaining allegations in this paragraph of the Complaint.

13 90. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
18 remaining allegations in this paragraph of the Complaint.

19 91. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
26 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
27 remaining allegations in this paragraph of the Complaint.

28

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1 92. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 93. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
14 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
15 paragraph of the Complaint.

16 94. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 95. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 96. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 97. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 **Response to Third Cause of Action: Breach of Express Warranty**

10 99. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
11 Complaint as if fully set forth herein.

12 100. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants admit that they provided FDA-approved
19 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
20 this paragraph of the Complaint.

21 101. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants admit that they provided FDA-approved
28

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1 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
2 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

3 102. Defendants admit that they provided FDA-approved prescribing information regarding
4 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
5 paragraph of the Complaint.

6 103. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 104. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 105. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
20 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants admit that they provided FDA-approved prescribing information regarding
24 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

1 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Fourth Cause of Action: Breach of Implied Warranty**

4 109. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
5 Complaint as if fully set forth herein.

6 110. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
8 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
9 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
10 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
11 Celebrex® in the United States to be prescribed by healthcare providers who are by law
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
13 the remaining allegations in this paragraph of the Complaint.

14 111. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit that they provided FDA-approved prescribing information regarding
19 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 112. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 113. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants admit that they provided FDA-approved
4 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
5 this paragraph of the Complaint.

6 114. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
8 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
9 Celebrex® was expected to reach users and consumers without substantial change from the
10 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 115. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
18 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

19 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
20 damage, and deny the remaining allegations in this paragraph of the Complaint.

21 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

26 119. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
27 Complaint as if fully set forth herein.
28

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1 120. Defendants state that this paragraph of the Complaint contains legal contentions to
2 which no response is required. To the extent that a response is deemed required, Defendants
3 admit that they had duties as are imposed by law but deny having breached such duties.
4 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
5 FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint, including all subparts.

16 122. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 123. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny any wrongful conduct, deny that

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1 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
2 paragraph of the Complaint.

3 124. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 125. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 126. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
19 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 127. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
27 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 128. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 129. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint.

21 130. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
23 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

1 131. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 132. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Sixth Cause of Action: Unjust Enrichment**

8 134. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
9 Complaint as if fully set forth herein.

10 135. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
11 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
12 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
13 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
14 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
15 Celebrex® in the United States to be prescribed by healthcare providers who are by law
16 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
17 the remaining allegations in this paragraph of the Complaint.

18 136. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
20 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 137. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 138. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
28 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for Relief,” including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’ Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

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First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed, and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or

omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes,

1 and Plaintiffs' causes of action are preempted.

2 **Twenty-third Defense**

3 23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary
4 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
5 issue under applicable federal laws, regulations, and rules.

6 **Twenty-fourth Defense**

7 24. Plaintiffs' claims are barred in whole or in part because there is no private right of
8 action concerning matters regulated by the Food and Drug Administration under applicable
9 federal laws, regulations, and rules.

10 **Twenty-fifth Defense**

11 25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate
12 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
13 of Comment j to Section 402A of the Restatement (Second) of Torts.

14 **Twenty-sixth Defense**

15 26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim
16 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of
17 Restatement (Second) of Torts § 402A, Comment k.

18 **Twenty-seventh Defense**

19 27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical
20 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
21 to § 6 of the Restatement (Third) of Torts: Products Liability.

22 **Twenty-eighth Defense**

23 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
24 Products Liability.

25 **Twenty-ninth Defense**

26 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead
27 facts sufficient under the law to justify an award of punitive damages.

28

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Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of North Carolina, Florida, and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and,

1 therefore, constitute protected commercial speech under the applicable provisions of the United
2 States Constitution.

3 **Thirty-eighth Defense**

4 38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly
5 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
6 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
7 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
8 Amendment of the United States Constitution, the Commerce Clause of the United States
9 Constitution, and the Full Faith and Credit Clause of the United States Constitution, and
10 applicable provisions of the Constitutions of the States of North Carolina, Florida, and
11 California. Any law, statute, or other authority purporting to permit the recovery of punitive
12 damages in this case is unconstitutional, facially and as applied, to the extent that, without
13 limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's
14 discretion in determining whether to award punitive damages and/or the amount, if any; (2) is
15 void for vagueness in that it failed to provide adequate advance notice as to what conduct will
16 result in punitive damages; (3) permits recovery of punitive damages based on out-of-state
17 conduct, conduct that complied with applicable law, or conduct that was not directed, or did not
18 proximately cause harm, to Plaintiffs ; (4) permits recovery of punitive damages in an amount
19 that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to
20 the amount of compensatory damages, if any; (5) permits jury consideration of net worth or
21 other financial information relating to Defendants; (6) lacks constitutionally sufficient standards
22 to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks
23 constitutionally sufficient standards for appellate review of punitive damages awards; and (8)
24 otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific*
25 *Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance*
26 *Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559
27 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

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Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Upon information and belief, Plaintiffs' claims may be barred by the provisions of N.C. Gen. Stat. § 99B-4(1) in that the use of the product may have been contrary to express and adequate instructions or warnings provided to Plaintiffs by their physician(s).

Fifty-ninth Defense

59. Upon information and belief, Plaintiffs continued to use Celebrex® after learning of its alleged defects. Accordingly, Plaintiffs' claims are barred by North Carolina common law and N.C. Gen. Stat. § 99B-4(2).

Sixtieth Defense

60. If it is discovered that Plaintiffs failed to exercise reasonable care under the circumstances in the use of Celebrex®, and Plaintiffs' failure was a proximate cause of Plaintiffs' alleged injuries, then the provisions of N.C. Gen. Stat. § 99B-4(3) are pled as a complete bar to Plaintiffs' right to recover against Defendants.

Sixty-first Defense

61. Plaintiffs' claims are barred by N.C. Gen. Stat. § 99B-5(c), which expressly limits Defendants' responsibility to provide product warnings directly to consumers of prescription drugs.

Sixty-second Defense

62. Plaintiffs' product liability claims are barred by the defenses recognized by N.C. Gen. Stat. § 99B-6, and all of its subparts.

Sixty-third Defense

63. To the extent not separately stated, Defendants plead as an affirmative defense all the applicable defenses provided in N.C. Gen. Stat. Ch. 99B.

1 **Sixty-fourth Defense**

2 64. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by
3 Rule 1.120 of the Florida Rules of Civil Procedure.

4 **Sixty-fifth Defense**

5 65. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and
6 marketed in accordance with the state of the art at the time of manufacture per § 768.1257,
7 Florida Statutes.

8 **Sixty-sixth Defense**

9 66. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable
10 because, at the time of sale or distribution of the Celebrex® alleged to have been used by
11 Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug
12 Administration and are entitled to application of § 768.1256, Florida Statutes.

13 **Sixty-seventh Defense**

14 67. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or
15 fault of Plaintiffs, or persons or parties whose identities are unknown at this time, and such
16 comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs'
17 recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced
18 as a result of the negligence or fault of said persons or entities, pursuant to the provisions of §
19 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§
20 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants'
21 percentage of fault, taking into account the percentage of fault attributable to all other persons,
22 whether or not a party hereto, and not on the basis of joint and several liability. The persons or
23 entities referred to in this paragraph that are presently unknown to Defendants will be identified
24 in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

25 **Sixty-eighth Defense**

26 68. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade
27 Practices Act ("FDUTPA").
28

Sixty-ninth Defense

69. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

Seventieth Defense

70. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

Seventy-first Defense

71. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with regard to Plaintiffs or otherwise.

Seventy-second Defense

72. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses, or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

September 25, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

September 25, 2007

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